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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,212	01/12/2006	Jose Maria Mato De La Paz	4258-112	5253

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,212	MATO DE LA PAZ ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2007*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 14-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8 and 14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1-5, 8, 14-18 is acknowledged and has been entered.

2. Applicant's cancellation of claims 6, 9-13 is acknowledged and has been entered.

3. Applicant's addition of claims 17, 18 is acknowledged and has been entered.

Rejections Withdrawn

4. Applicant's arguments, see amended claims, filed April 6, 2007, with respect to the rejection of claims 1-7, 9, 10, and 16 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 1-7, 9, 10, and 16 under 35 U.S.C. 112, second paragraph, has been withdrawn.

5. Applicant's arguments, see amended claims, filed April 6, 2007, with respect to the rejection of claims 1-7, 9, 10, and 16 under 35 U.S.C. 102(e) as being anticipated by Rose et al. [US 2006/0084067] and under 35 U.S.C. 102(a) as being anticipated by Santamaria et al. [Santamaria et al., Functional proteomics of nonalcoholic steatohepatitis : mitochondrial proteins as targets of S-adenosylmeth8ionine, March 2003, PNAS, 100(6), p.3065-3070] have been fully considered and are persuasive. The rejection of claims 1-7, 9, 10, and 16 under 35 U.S.C. 102(a) and35 U.S.C. 102(e) has been withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 8, 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assessing a subject to identify presence of NASH in said subject, does not reasonably provide enablement for identifying susceptibility to NASH in said subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to perform the invention commensurate in scope with these claims. In particular, applicant does reasonably provide support for determining how one would determine if a subject is susceptible to NASH, or even what would constitute susceptibility. Since any subject is potentially capable of developing NASH, technically there would be no basis in differentiating between "normal" subjects and those "susceptible" to NASH.

8. Furthermore, applicant has not recited any limitations as to what comparisons to make to determine that a subject is susceptible to NASH, as opposed to determining that the subject already has NASH, or that the subject is normal. Neither was this guidance found in the specification, rendering it difficult for one of ordinary skill in the art to determine what diagnosis to give to a subject based on comparison with reference data. For example, it is unclear if the subject would be considered normal if only some of the markers differed from their reference values. Another example would be if all the markers were different, it is unclear whether the subject would have NASH, or would merely be susceptible to NASH, or if a diagnosis could even be made. In particular, if the values of the markers were different from not only the normal reference values, but also different to the values from a subject with NASH, it is unclear what kind of diagnosis would be made.

9. The Office also notes that throughout the specification, applicant appears to treat the mice that are susceptible of developing NASH with those that have developed NASH as a single group, rendering it unclear how the two groups are differentiated. Furthermore, in all the cases presented by applicants, the data used to determine susceptibility or presence of NASH are obtained by mice deficient in MAT1A gene, and who are therefore bound to develop NASH. It is unclear how relevant these results would be in determining the susceptibility to NASH in mice who are not deficient in MAT1A gene, and more importantly in determining the susceptibility to NASH in the average human.

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
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